Clinical Research Coordinator

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Course Overview

The *Clinical Research Coordinator Course* provides a practical understanding of the key responsibilities involved in coordinating and managing clinical trials. It covers essential aspects such as protocol development, participant recruitment, informed consent, investigational product management, data handling, and site documentation. The course emphasises quality assurance, ethical conduct, and compliance with national and international regulations, ensuring coordinators uphold the highest standards in clinical research.

Participants will gain insight into the full trial process, from feasibility and study start-up to monitoring and close-out, while also developing core skills in communication, teamwork, and leadership. Combining theory and practice, the course equips delegates with the knowledge and confidence to manage day-to-day site operations effectively and contribute to the integrity and success of clinical studies.

Certification

- Delegates are required to complete a final assessment with at least 70% accuracy.
- Upon successful completion of the course, the delegate will be given access to the Clinical Research Coordinator Certificate of Completion.

CPD Points

- CPD points will be issued with the certificate of completion.

Target Audience

The target audience includes clinical research coordinators, study nurses, investigators, and other research professionals involved in the day-to-day management and conduct of clinical trials.

It is also suitable for individuals new to clinical research who wish to gain a comprehensive understanding of study coordination and site operations.

Duration

The classroom training is three (3) full days (from 08h30 to 16h00).

Cost

Classroom

WHC	R5,355.00	No Vat
Wits	R5,355.00	Vat Incl
Private	R5,355.00	Vat Incl

In-house training will be considered, subject to viability.

This course is delivered by Chameleon Clinical Research Consultant and managed by Academic Advance.

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Learning Outcomes

General Competency Domains Covered Throughout the Course

- Scientific concepts and research design
- Ethical and participant safety considerations
- Investigational product development and regulation
- Clinical trial operations (GCP)
- Study and site management
- Data management and informatics
- Leadership and professionalism
- Communication and teamwork

Module 1: Introduction to Clinical Research

- Understand the fundamentals of clinical study design, including observational and experimental (interventional) studies, randomisation, blinding, and phases of clinical trials.
- Learn about the roles and responsibilities of sponsors, investigators, and regulatory authorities.
- Gain knowledge of Good Clinical Practice (GCP) principles, their historical development, and their application in South Africa (SA GCP).
- Recognise the importance of human subject protection, informed consent, and ethical conduct in research.
- Become familiar with essential documents, investigator files, and regulatory requirements for clinical trials.
- Develop skills in protocol development, version control, and the use of manuals of procedures (MOP) and standard operating procedures (SOPs).
- Understand the structure and content of clinical research protocols and the process for protocol amendments and training.

Module 2: The Important Role of the CRC / Pre-Study Phase

- Define the Clinical Research Coordinator (CRC) role as the central point of contact and protocol expert at the site.
- Identify the skills and knowledge required for CRCs, including communication, problem-solving, organisational, and clinical competencies.
- Learn the steps in the pre-study phase: feasibility assessment, budget and funding, stakeholder engagement, and application for regulatory and ethics approval.
- Understand the process for setting up the research team, facilities, and documentation systems.
- Develop strategies for participant recruitment and retention, including planning, tracking, and addressing recruitment challenges.
- Prepare for site initiation visits and ensure all approvals, documentation, and resources are in place before study start.
- Gain practical experience through exercises in team selection, enrolment projection, and checklist development.

Module 3: Study Conduct Phase

- Emphasise the importance of quality, ethical conduct, and systematic processes during study implementation.
- Prepare for and participate in site initiation visits, including staff training and readiness assessments.
- Manage participant recruitment, screening, randomisation, and retention using effective strategies and tracking tools.
- Conduct informed consent processes, ensuring comprehension, voluntariness, and proper documentation.
- Implement clinic flow improvements, checklists, and chart notes to optimise participant visits and data quality.
- Complete and manage Case Report Forms (CRFs), both paper and electronic, ensuring data accuracy and compliance with GCP.
- Report and manage adverse events (AEs), serious adverse events (SAEs), and safety oversight, including Data and Safety Monitoring Plans (DSMP).
- Apply quality management principles, including Clinical Quality Management Plans (CQMP), monitoring, audits, and inspections.
- Develop strong communication skills for team management, stakeholder engagement, and community outreach.
- Manage staff, coordinate tasks, and maintain financial oversight throughout the study.

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Learning Outcomes

Module 4: Study Termination Phase

- Prepare for study close–out by creating checklists for participant exit visits and site closure.
- Ensure all data, documentation, and study products are accounted for and reconciled.
- Manage the archiving of essential documents and data according to regulatory and sponsor requirements.
- Oversee the dissemination of study results to stakeholders, participants, and the public, and understand publication policies.
- Complete the clinical study report, summarising methods, results, and regulatory submissions.
- Address site close–out procedures, including sponsor/monitor visits, close–out letters, and compliance with SA GCP guidelines.
- Understand procedures for premature termination, including notification, documentation, and regulatory reporting.

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